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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--------------------------|---------------------------------|-----------------------------|
| 10/802,970 | 03/16/2004 | Carl-Magnus A. Andersson | ACADIA.014C2 | 5078 |
| 20995 7590 10/25/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | EXAMINER MABRY, JOHN | |
| | | | ART UNIT 4133 | PAPER NUMBER |
| | | | NOTIFICATION DATE 10/25/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/802,970 | Applicant(s) ANDERSSON ET AL. | |
| | Examiner John Mabry | Art Unit 4133 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 and 53-60 are drawn to compounds of Formula I, wherein Z = piperidinyl (n=1), (fused/non-fused), X1=C, Ar1 and Ar2=phenyl and pharmaceutical compositions thereof classified in class 546, subclass 247. A further election of a single disclosed species is required.
- II. Claims 1-5, 7-12, 14 and 53-65 are drawn to compounds of Formula I, wherein Z = piperidinyl (n=1), (fused/non-fused), X1=N, X2=-CH2-, Ar1 and Ar2 = phenyl and pharmaceutical compositions thereof classified in class 564, subclass 56. A further election of a single disclosed species is required.
- III. Claims 1-4, 8-12, 14 and 54 are drawn to compounds of Formula I, wherein Z = pyrrolidinyl (n=0), and pharmaceutical compositions thereof classified in class 548, subclass dependent on species elected. A further election of a single disclosed species is required. This group may be subject to further restriction.

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- IV. Claims 1-4, 8-11, 14 and 58 are drawn to compounds of Formula I, wherein Z = azepanyl ($n=2$), and pharmaceutical compositions thereof classified in class 540, subclass dependent on species elected. A further election of a single disclosed species is required. This group may be subject to further restriction.
- V. Claims 1-14 and 53-65 are drawn to compounds of Formula I that are not encompassed by Groups I-IV and pharmaceutical compositions thereof classification is dependent on species elected. A further election of a single disclosed species is required. This group may be subject to further restriction.
- VI. Claims 15-52 and 66-77 are drawn to a method of treatment of inhibiting monoamine receptors and serotonin receptors for treatment of related disorders and diseases thereof limited to the scope of Group I, classified in class 514, subclass dependent on the species elected. An election of a single disclosed species for use in this method is also required.
- VII. Claims 15-52 and 66-77 drawn to a method of treatment of inhibiting monoamine receptors and serotonin receptors for treatment of related disorders and diseases thereof limited to the scope of Group II, classified in class 514, subclass dependent on the species elected. An election of a single disclosed species for use in this method is also required.

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- VIII. Claims 15-52 and 66-77 drawn to a method of treatment of inhibiting monoamine receptors and serotonin receptors for treatment of related disorders and diseases thereof limited to the scope of Group III, classified in class 514, subclass dependent on the species elected. An election of a single disclosed species for use in this method is also required.
- IX. Claims 15-52 and 66-77 drawn to a method of treatment of inhibiting monoamine receptors and serotonin receptors for treatment of related disorders and diseases thereof limited to the scope of Group IV, classified in class 514, subclass dependent on the species elected. An election of a single disclosed species for use in this method is also required.
- X. Claims 15-52 and 66-77 drawn to a method of treatment of inhibiting monoamine receptors and serotonin receptors for treatment of related disorders and diseases thereof limited to the scope of Group V, classified in class 514, subclass dependent on the species elected. An election of a single disclosed species for use in this method is also required.

The inventions are distinct, each from the other because of the following reasons:

Groups I – V are independent and distinct from each other as they are drawn to compounds of formula I with different divergent moieties in the X1, X2, Y1, Y2, Ar1, Ar2, W and Z positions. Group I requires compounds of Formula I wherein, Z = piperidinyl

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(n=1), (fused/non-fused), X1=C and Ar1 and Ar2=phenyl. Group II requires compounds of Formula I wherein, Z = piperidinyl (n=1), (fused/non-fused), X1=N and X2=-CH2- and Ar1 and Ar2=phenyl. Group III requires compounds of Formula I wherein, Z = pyrrolidinyl (n=0). Group IV requires compounds of Formula I wherein, Z = azepanyl (n=2). Group V requires compounds of Formula I that are not encompassed by Groups I-IV.

The compounds of group V do not fall within groups I – IV. Each of groups I - V are directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. Each of groups I – V have different classifications and subclasses. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in groups I - V, these inventions are distinct.

Inventions I - V and VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case Groups I - V are drawn to compounds and pharmaceutical compositions thereof of Formula I. Groups VI-X are drawn to a method of treatment of inhibiting monoamine receptors and serotonin receptors for treatment of related disorders and diseases thereof using one of compounds Groups I - V.

In this instance, the method of treatment can be practiced with another materially different product. For example, Behan et al have disclosed a class of pyrazole compounds which act as 5-HT_{2A} receptor inverse agonists (see U.S. 6,107,324). This is just one method of treatment.

Because these inventions are distinct for the reasons given above and the search required for group I is not required for groups II - X, restriction for examination purposes as indicated is proper. Groups I - X are not identically classified under U.S. Patent Classification guidelines, thus, to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together.

Thus, groups I - X have been appropriately restricted on the basis of being both independent or distinct and presenting an unduly search burden on the Examiner if they were to be searched together.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

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may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007.

Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the

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elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Conclusion

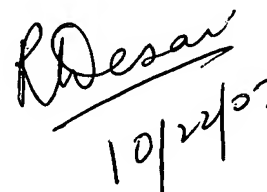
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JM



RITA DESAI
PRIMARY EXAMINER